

Message

From: Biggio, Patricia [biggio.patricia@epa.gov]
Sent: 7/7/2020 5:42:31 PM
To: Saunders, Jennifer [Saunders.Jennifer@epa.gov]; Metzger, Autumn [Metzger.Autumn@epa.gov]
CC: Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: RE: TCVP collar amendment efficacy "screen"
Attachments: RE: CDX PSP Package Transmitted to OPP; Re: CDX PSP Package Transmitted to OPP; Re: TCVP Submission (continued)

Flag: Follow up

Hi all,

Something that we may have to keep in mind for TCVP...Hartz was working with Information Services to switch out some labels (see attached emails). We have those labels by email, but I'm not sure if they made it to Documentum yet (screenshot below). The folders in should have everything from both email and Documentum (labels, application form, etc):

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Thank you,
Trish

Search Results

1 Results for "2596-48" in folder - 7/7/2020 5:29 PM

File Name	Size	Modified	Version
2596-48	20 KB	7/7/2020 9:44 AM	CURRENT, 1.0
2596-48	178 KB	7/7/2020 9:44 AM	1.0, CURRENT
2596-48	156 KB	7/7/2020 9:44 AM	CURRENT, 1.0
2596-48	425 KB	4/4/2019 12:28 PM	1.0, CURRENT

From: Biggio, Patricia
Sent: Tuesday, July 7, 2020 12:17 PM
To: Saunders, Jennifer <Saunders.Jennifer@epa.gov>; Metzger, Autumn <Metzger.Autumn@epa.gov>
Cc: Manupella, Matthew <Manupella.Matthew@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Friedman, Dana <Friedman.Dana@epa.gov>
Subject: RE: TCVP collar amendment efficacy "screen"

Hi all,

Please find attached Hartz's efficacy bridging rationale, which cites Registration Nos 2596-83 and 2596-84 in the narrative.

Ex. 5 Deliberative Process (DP)

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Each collar and it's respective amendment documents may be found in individual folders at the following link. We are checking Documentum for what has been submitted. Courtesy copies may already be in these folders.

Ex. 5 Deliberative Process (DP)

We are developing a tracker to follow these amendments, which may be found here:

Ex. 5 Deliberative Process (DP)

I thought of trying to send a link to the respective product folders before sending RD all of the labels at once. Here is a breakdown of how the collars are being amended:

- 2596-49: Weight restriction
- 2596-50: Collar redesign
- 2596-62: Collar redesign
- 2596-63: Voluntary cancellation
- 2596-83: Collar redesign and weight restriction
- 2596-84: Collar redesign
- 2596-139: Collar redesign and weight restriction

Hartz did have a question regarding data for these collars (from the attached email): *"I do have a question and would appreciate guidance for the portal submission; since there are a number of collar registrations 2596- 49; -50; -62; -83;-84 and -139 which will be using the submitted study data can we agree that data will only be filed to Registration No. 2596-139 and remaining registration will reference the EPA assigned MRID number.. I will include this email and your response along with a cover letter in the portal filing understanding that a single data submission satisfies all of the remaining collar registrations.."*

Thanks all, please let me know if you would like to discuss further.

-Trish

From: Saunders, Jennifer <Saunders.Jennifer@epa.gov>

Sent: Thursday, July 2, 2020 9:28 AM

To: Friedman, Dana <Friedman.Dana@epa.gov>

Cc: Biggio, Patricia <biggio.patricia@epa.gov>; Manupella, Matthew <Manupella.Matthew@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Metzger, Autumn <Metzger.Autumn@epa.gov>

Subject: RE: TCVP collar amendment efficacy "screen"

Much appreciated! Autumn will take a look when the data is sent (feel free to send as a response to this email so it's all in one place) and she's back next week. Have a great 4th!

From: Friedman, Dana <Friedman.Dana@epa.gov>

Sent: Thursday, July 02, 2020 9:23 AM

To: Saunders, Jennifer <Saunders.Jennifer@epa.gov>

Cc: Biggio, Patricia <biggio.patricia@epa.gov>; Manupella, Matthew <Manupella.Matthew@epa.gov>; Johnson, Marion

<Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Metzger, Autumn <Metzger.Autumn@epa.gov>

Subject: TCVP collar amendment efficacy "screen"

Internal, Deliberative

Jenn, please see responses below --

From: Saunders, Jennifer <Saunders.Jennifer@epa.gov>

Sent: Wednesday, July 01, 2020 1:17 PM

To: Friedman, Dana <Friedman.Dana@epa.gov>

Cc: Biggio, Patricia <biggio.patricia@epa.gov>; Manupella, Matthew <Manupella.Matthew@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Metzger, Autumn <Metzger.Autumn@epa.gov>

Subject: efficacy "screen"

Ex. 5 Deliberative Process (DP)

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